

DOCKET NO.: 133816.01101

PATENT

REMARKS

Claims 17-24, 26-31, 33, 38, and 41-44 are currently pending. All pending claims stand rejected.

Claims 17, 21, 24, 41, 43, and 44 are hereby amended. The amendments are supported by the application throughout and the originally filed claims. No new matter has been added as a result. Claims 18-20, and 30 are hereby canceled. Applicants reserve the right to pursue subject matter of the canceled claims in a continuation application.

Applicants respectfully acknowledge the withdrawal of the outstanding objection to the specification. Additionally, Applicants submit that claim 41 is amended to include "comprising" in order to clarify the claimed invention. The basis for the rejection under section 112, second paragraph is now moot.

Enablement and Written Description under Section 112, First Paragraph

Claims 17-24, 26-31, 33, 38, and 41-44 stand rejected under section 112, first paragraph, for lack of enablement. Additionally, claims 17-18, 24, 27-31, 33, 38, 41, 42, and 44 stand rejected under section 112, first paragraph, for failing to comply with the written description requirement. Applicants traverse these rejections.

Applicants submit that in view of the amendments herein the claimed invention is related to a method for stimulating angiogenesis by injecting an isolated nucleic acid expression construct, which comprises "a nucleic acid sequence encoding an insulin-like growth factor I." The additional language directed to "functional biological equivalent" and "xx% similar" have been removed. As a result, the alleged breadth issues cited in the outstanding Office Action (see page 4, for example) have been addressed, and the basis for these rejections have been removed. The claimed invention is fully supported by the specification, as admitted by the Patent Office in the previous Office Action and in the outstanding Office Action (See paragraph bridging page 3 and 4, and second sentence of first complete paragraph on page 4).

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Accordingly, Applicants respectfully request the outstanding rejections based on section 112, first paragraph, to be withdrawn.

Rejection under Section 102(b) over Alila et al. Hum. Gene Therapy 8:1785-1795, 1997 ("the Alila reference")

Claims 17, 19-21, 31, 33, 38 and 42 stand rejected under section 102(b) over the Alila reference. Applicants respectfully traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). See MPEP § 2131. The Alila reference fails to disclose each and every element of the claimed invention.

The claimed invention is directed to methods of "stimulating angiogenesis in a subject who as a muscle injury" and such is not disclosed in the Alila reference. Also, the claimed invention is directed to methods that include the step of "injecting into muscle tissue of the injured muscle of the subject an isolated nucleic acid expression construct", and again the Alila reference fails to disclose such a step. The Alila reference does not disclose each and every element.

The Patent Office on page 7 of the outstanding Office Action states that "Alila teach that using their method, one could treat local myoncuropathies" citing to p. 1794, 1st col., last paragraph of the Alila reference. However, the Alila reference actually states that "Gene therapy using formulated plasmids may have potential utility in the treatment of local myoncuropathies by increasing tissue concentration of hIGF-I or other growth factors in the affected muscles without systemic effects." (emphasis added). One of ordinary skill would understand this passage to suggest further experimentation to determine if one of many growth factors could have utility in the treatment of local myoncuropathies. Such suggestions fail to place the claimed invention in the possession of one of ordinary skill. As such, the Alila reference fails to anticipate the claimed invention.

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Accordingly, Applicants submit that the Alila Reference fails to anticipate the claimed invention; therefore this rejection should be withdrawn.

Rejection under Section 103 over the Alila reference in View of van Deutekom et al, Mol. Med. Today, 214-220 (1998) (the "van Deutekom reference")

Claims 22-23 stand rejected as rendered obvious over the Alila Reference in view of the van Deutekom Reference. The Applicants respectfully traverse.

As a preliminary matter, the 103(a) rejection is improperly based upon inherency and should be withdrawn. It is well established that the obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kuhn*, 441 F.3d 977, 986, 78 USPQ 1329,1335 (Fed. Cir. 2006). Relying on inherency to support a finding of obviousness is improper because inherency and obviousness are distinct concepts. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983) (citing *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966) in finding a 103(a) rejection based upon inherency to be improperly issued).

The Office has stated that "the property of stimulating angiogenesis is an inherent property of IGF-1." (Office Action, page 10). The Office asserts that this alleged inherent property provides a motivation to modify the cited references. Such a reliance on alleged inherent properties is improper. Therefore, the Office has failed to properly establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Applicants respectfully request that the rejection be withdrawn.

The rejection is also improper because the references fail to support an objective reason to combine and modify the reference and fail to disclose all of the elements of the claims. Applying the arguments of the above-section directed to the anticipation rejection, the Alila reference fails to disclose the claimed invention directed towards methods of stimulating angiogenesis with the provided nucleic acid expression constructs. The van Deutekom reference fails to make up for this absent teaching.

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In addressing the inherency basis for this rejection, Applicants point to Section 2112 of the M.P.E.P., which sets forth the standard for inherency as follows:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). >"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" (underlining original).

There is no inherent disclosure of stimulating angiogenesis in a subject who has a[n] muscle injury with a method that includes injecting into muscle tissue of the injured muscle of the subject an isolated nucleic acid expression construct. The allegation that the property of stimulating angiogenesis is an inherent property of IGF-I still does not amount to the aforementioned method is necessarily present in the disclosure of the Alila reference.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Rejection under Section 103 over the Alila reference in View of Draghia-Akli, Fewell and Isner.

Claims 18, 24, 26-30, 41, 43, and 44 stand rejected under section 103 over the above-combination of cited references. Applicants respectfully traverse.

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Claims 18 and 30 have been canceled.

Again, applying the arguments of the above-section directed to the anticipation rejection, the Alila reference fails to disclose the claimed invention directed towards methods of stimulating angiogenesis with the provided nucleic acid expression constructs. The secondary references cited herein fail to make up for the deficiencies of the Alila reference. As a result, these cited references, alone or in combination, fail to render the claimed invention obvious.

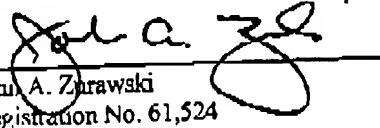
Accordingly, it is respectfully requested that this rejection be withdrawn.

Conclusion

Applicants respectfully submit that, in light of the foregoing comments and amendments, all pending claims are now in condition for allowance. A Notice of Allowance is therefore requested.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436. If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully Submitted,


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Dated: August 11, 2008
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